

Remarks

Please cancel claims 21-22. Please add claims 31 and 32. Please amend claims 1 and 14. Support for this amendment is found at paragraph 17 of the specification.

Claims 1, 6, 9, 14-20 and 27 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Young in view of Iovanna, Valter, Jorgensen, and Haddad.

Applicants arguments with respect to this rejection and its (inappropriate) reliance on anticipatory inherency were explained in the Reply filed 6/30/09. These arguments are specifically relied on and the issue reserved for appeal. With respect to the rejection mailed 11/17/09 and the reply to Applicant's arguments submitted 6/30/09, the cited references provide no disclosure regarding the treatment of pancreatitis by administering amylin or an amylin analog, and nor does any cited reference or combination provide a motivation to treat pancreatitis with amylin or an amylin analog. The logic of the rejection appears to be that the motivation is to treat the pain associated with pancreatitis, and by so doing one is inherently treating the pancreatitis. But this position has no legal foundation because inherency is a concept in anticipation, and there is no legal doctrine of obviousness by inherency. Furthermore, as explained in detail in the Reply filed 6/30/09, the requirements even of the inappropriately applied anticipatory inherency doctrine are not met in the present case. Therefore, the rejection has no legal basis and reconsideration is respectfully requested.

As explained by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007), the appropriate analysis is to apply the *Graham* factors, which are the controlling inquiries in any obviousness analysis. Thus the scope and content of the prior art must be considered, the differences between the claimed invention and the prior art ascertained, and resolving the level of the person of ordinary skill in the art. When such analysis is performed here it is seen that no cited reference or any combination of them teaches or suggests that amylin or an amylin analog may be useful in the treatment of pancreatitis.

Additionally, the present claim recites that the method is for treating pancreatitis in a mammalian subject afflicted with pancreatitis. Thus, the claim requires that the methods be

performed on a subject actually afflicted with pancreatitis. The Federal Circuit has held that where a claim was drawn to treating or preventing a specific disease and where the claim required that the active ingredient be administered "to a human in need thereof," that the need must be recognized and appreciated for the claim to be infringed. *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 68 USPQ2d 1154 (Fed. Cir. 2003). In the present case the claims are drawn to treating pancreatitis in a subject that is afflicted with pancreatitis. And in like manner these claims require that the need be recognized and appreciated and that the subject be afflicted with pancreatitis, and that the amylin or amylin agonist be administered for the purpose of treating the pancreatitis. *Jansen* ("The preamble is ... a statement of the intentional purpose for which the method must be performed"). Since none of the cited references, nor any combination thereof, teach or suggest such a treatment, the claims are not rendered obvious by the cited references.

Closing

If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No fees are believed due with this submission in addition to those otherwise provided for herein. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 0101-UTL-0. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535. Any required petitions are hereby constructively petitioned.

Date: Feb. 17, 2010

Respectfully submitted,



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